Minutes of the Environmental Health Committee Meeting

August 30, 2000

U.S. Environmental Protection Agency
Science Advisory Board
International Trade Commission building, Washington DC

The Environmental Health Committee (EHC) of the US EPA Science Advisory Board (SAB) met on August 30, 2000, at the International Trade Commission building, 400 E Street, S.W., Washington DC. The meeting was announced in the Federal Register at FR Vol. 65, Number 152, August 7, 2000, pp. 48238-48239 (Attachment A). The proceedings followed the agenda (Attachment B) with minor deviations. The purpose of the meeting was to review an EPA report to the Congress on the Integrated Risk In formation System (IRIS). The Agency sought advice from the EHC on three major issues:

a) How well did the study conform to the study plan developed with the SAB EC (November 1999 and March 2000)?

b) Does the SAB concur with the findings of the reviewers?

c) What further improvements, if any, might the Agency make in IRIS documentation in response to the study results?

Convene the Meeting, Dr. Mark Utell, Chair, convened the meeting at 9:00 a.m. and welcomed all the attendees. After a brief discussion of administrative issues and the Federal Advisory Committee Act (FACA) and its requirements by the Designated Federal Officer (DFO), the Chair asked each Member, Consultant, and Federal Expert on the Subcommittee to identify him/her self, their organizational affiliation, research interests, and to state if they had identified any possible conflict of interest concerning the matters to be discussed by the Subcommittee. No such issues were identified.

The following Members and Consultants served on the SAB/SAP Joint Subcommittee: Drs. Mark Utell (Chair), Stephen L. Brown, John Doull , George Lambert, Grace K. Lemasters, Abby A. Li, Michele Medinsky, and Roy E. Shore. Mr. Samuel Rondberg served as the Committee Designated Federal Officer. The Subcommittee roster is provided as Attachment C

Agency staff and public attendees are noted on the sign in sheets (Attachment D)

Background of the Issues

The meeting opened with the presentations by EPA staff (Drs. William Farland and Amy Mills, EPA National Center for Environmental Assessment) on the major issues ((handouts incorporated as Attachment E).

The following members of the public then addressed the meeting (handouts incorporated as Attachment F): Drs. Neil Roth, Daniel Byrd (CITRAPS), and Robert Conrad (American Chemistry

Council).

Following the Public Comment, the Subcommittee turned to the substantive issues for the review. The following brief paragraphs attempt to capture the overall conclusions (or lack thereof) of the Subcommittee=s deliberations on each issue, not every nuance raised in the course of (frequently) lengthy discussions.

Issue1 asked how well the study conformed to the study plan developed through consultation with the SAB EC. The Lead Discussant was Dr. Zeise, with Dr. Doull as Associate. The Committee agreed that the Agency did a good job implementing the study plan laid out in the July 19 NCEA report, in terms of the number of reviewers evaluating each IRIS chemical assessment, randomized process for selection of chemicals, number of chemicals evaluated, selection of reviewers and overall scope of the review. One significant deviation from the NCEA plan was in the number of IRIS substances selected with Aextensive@ and Asome@ documentation of uncertainty in the Apre-pilot@ and Apilot/post-pilot@ groups. The EHC found this to be, however, a reasonable deviation from study plan.

The Committee has some other comments on the implementation of the study plan:

a) Although the definition of Auncertainty@ used for the study followed that used by the risk assessment community, the definition of Avariability@ did not. The importance of keeping the two terms distinct when assessing and describing risk has been previously emphasized. The definition of variability used in the study may be seen as overly broad, but could have resulted from an interpretation of the Congressional language calling for an evaluation of the IRIS documentation of Athe range of uncertainty and variability of the data.@

   This issue led some SAB participants to express concern that the study did not fully address what may have been (or, to speculate, perhaps should have been) the underlying concern of Congress. Congress asked about "uncertainty and variability of the data." However, since neither the Congress nor the EPA study plan provided a completely satisfactory definition of those terms, EPA chose to interpret the Congressional request to apply mainly to the information underlying the IRIS values, not to the values themselves. An alternative and more salient interpretation would focus on the extent to which the IRIS documentation provides a) a reasonable description of the intrinsic uncertainty in a given human health risk assessments, and b) an estimate of the extent of variability of human risk.

b The study was not implemented to review adequately IRIS qualitative or quantitative

descriptions of interindividual differences in susceptibility. Evaluation of IRIS descriptions of individual susceptibility and variability in risk with different life stages would have been consistent with the study plan.

The second issue asked if the Committee concurred with the findings of the reviewers. The Lead Discussant was Dr. Shore, with Drs. Li and Medinsky as Associates. The Committee agreed that the reviewers had followed their mandate and reached overall conclusions that were reasonable. The EHC noted that the findings of reviewers on specific points varied, in several cases considerably, even when the discussions of uncertainty were extensive. This was to be expected. There is not currently any scientific consensus on how uncertainty in risk should be described, and practitioners of risk assessment differ on what constitutes a good and adequate discussion of uncertainty. Still, the Committee concurred with the general conclusion that the description of uncertainty could be significantly improved for most pre-pilot chemicals, and that such descriptions have improved significantly since the initiation of the pilot program. The Committee also agreed with the report=s general recommendations for improvement of characterizations of uncertainty and variability.

The third element of the Charge asked what further improvements, if any, might the Agency make in IRIS documentation in response to the study results. The Lead Discussant was Dr. Brown; Dr. Lemasters served as Associate. The Committee felt that IRIS= characterizations of data uncertainty and variability could be strengthened, and that a greater effort needs to be directed to address this important issue. Priority should be given to chemicals for which controversy over the IRIS evaluations is most acute. EPA might look at the discrepancies between the EPA evaluators and the expert peer panel evaluations of the study sample to help in refining the protocol. The Committee also urged EPA to a) develop a detailed protocol for completing an adequate documentation of uncertainty and variability and then rigorously train the managers of IRIS assessments in that protocol; and b) develop a strategy for *reducing* uncertainties where these severely compromise the utility of IRIS evaluations.

More broadly, the Committee also suggested that EPA investigate the feasibility of providing more information that can help answer the underlying question about the uncertainties and variabilities in human health risk assessments based on the IRIS toxicity numbers. One proposal suggested by some Committee Members was to characterize the toxicity of chemicals through distributional analyses of toxicity, as well as of exposure, in human health risk assessments. The mandate for adding new agents, plus the need to revise the documentation on the current agents, exceeds the resources allocated by the EPA to this task, and the Committee noted that the Congress might consider providing additional resources which are earmarked for improving IRIS. In the interim, the Agency should consider collaborative efforts with outside institutions, such as the National Academy of Sciences to expedite the generation of IRIS files. EPA could provide Internet as well as the Federal Register listings of the current status of updates and prioritization information. The Committee noted that here is considerable

overlap between IRIS toxicology reviews and the Agency for Toxic Substances and Disease Registry (ATSDR) Toxicology Profiles, the International Agency for Research on Cancer (IARC) cancer documents, the EPA=s Acute Exposure Guideline Level program documentation, the documentation for national and international occupational exposure levels, and the World Health Organization and the Organization for European Community Development databases as well as those created and maintained by state governments, environmental groups, industry, and other list generating groups. The IRIS staff should make the best possible use of the IARC, ATSDR, and other documents so as to avoid duplication of effort and make their own reviews easier to conduct, and should also seek to cross-reference these other reviews.

Finally, the Committee noted that the contract reviewers only occasionally discussed whether or not the IRIS files cited children as a subpopulation that might be more sensitive than the general population, and that the ORD/NCEA summary did not mention this issue at all. This issue is central to whether or not the uncertainty factors assigned for intraspecies (human) variability are sufficient to cover such potential childhood sensitivity. EPA needs to decide how it will deal with the concern that children might be at greater risk from certain environmental chemicals than adults.

Following discussion of report preparation, and the need for early completion of the report, the Chair adjourned the meeting at 3:55PM.

I certify that these minutes are accurate to the best of my knowledge.

/s/

Dr. Mark Utell
Chair

/s/

Mr. Samuel Rondberg
Designated Federal Officer